



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 20 1999 1619 '99 SEP 21 11:46

Mr. Thomas Morley
1472 West Larpenteur, #10
St. Paul, Minnesota 55113

Dear Mr. Morley:

Thank you for your letter of May 19, 1999, addressed to Senator Paul Wellstone concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation. Senator Wellstone has asked us to respond directly to you.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients" FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation, Title 21 Code of Federal Regulations, § 179, is enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR was extended to July 19, 1999.

We have forwarded your correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of

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irradiated foods will take into account all of the data and information received.

Because you may be concerned about irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this information responds to your concerns.

Sincerely,

for Jane F. Kirby
Melinda K. Plaisier
Interim Associate Commissioner
for Legislation

Enclosures

cc: Dockets Management Branch
(98N-1038)

The Honorable Paul Wellstone
United States Senate
Washington, D.C. 20510-2303

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1472 W Larpenteur #10
St. Paul, MN 55113
May 19, 1999

Senator Paul Wellstone
Senate
Washington, D.C.

Dear Senator Wellstone:

I am very concerned about the likelihood that some foods, mostly meats, will be irradiated for preservation purposes.

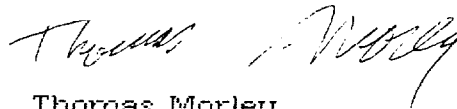
I suspect that this is a dangerous procedure.

I urge you, insist that all irradiated foods be plainly labelled as such, so that people can avoid them if they so desire.

Irradiated but unmarked foods are a menace, as I see it.

Don't believe the "authorities" if they tell you this is a harmless procedure. They have a vested interest in saying so, but there is evidence that says it is not harmless.

Sincerely yours,


Thomas Morley

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